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November 7, 2006

~~MSB~~ Stop Appeal Brief - Patents
Commissioner For Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: Applicant(s): Donohoe, Brendan M., et. al.
Assignee: Cardica, Inc.
Title: Method and Apparatus for Creating an Opening in the Wall of a Tubular Vessel
Serial No.: 10/054,745
Examiner: Vy Q. Bui Filed: January 22, 2002
Docket No.: 057 Group Art Unit: 3731

Dear Sir:

Transmitted herewith are the following documents in the above-identified application:

- (1) Return Receipt Postcard;
 - (2) This Transmittal Letter; and
 - (3) Appeal Brief Under 37 CFR 41.37 (Corrected).

Small entity status is not claimed in this application.

- Conditional Petition for Extension of Time: If an extension of time is required for timely filing of the enclosed document(s) after all papers filed with this transmittal have been considered, an extension of time is hereby requested.

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~~Respectfully submitted,~~

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Cardica, Inc.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Donohoe, Brendan M.; et. al.
Assignee: Cardica, Inc.
Title: Method and Apparatus for Creating an Opening in the Wall of a Tubular Vessel
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APPEAL BRIEF UNDER 37 CFR §41.37 (CORRECTED)

This Appeal Brief is prepared and submitted pursuant to the Notice of Appeal filed in this case on June 29, 2006 and the Notification of Non-Compliance mailed on October 30, 2006.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardica, Inc., as named in the caption above.

II. RELATED APPEALS AND INTERFERENCES

No pending appeals, interferences or other judicial proceedings, or prior interferences or other judicial proceedings, are known to Appellant, Appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by, or have a bearing

on the decision by the Board of Patent Appeals in this appeal. Appellant previously appealed a final rejection in this patent application by Notice of Appeal filed on December 10, 2004. However, that appeal did not proceed to the Board of Patent Appeals and Interferences, because prosecution was reopened by the Examiner. As a result, no court or Board has rendered a decision pertaining to this patent application, and no such decisions can be provided in the Related Proceedings Appendix.

III. STATUS OF CLAIMS

Claims 1-15, 17-31, 33-39 and 51 stand finally rejected. Claims 32 and 40-50 have been objected to. These claims are set forth in the appendix attached hereto.

Claims 16 and 52-61 have been withdrawn. These claims are not at issue and are not set forth in the appendix attached hereto.

IV. STATUS OF AMENDMENTS

No amendments were filed after final rejection or are currently pending in this case.

V. SUMMARY OF THE INVENTION

A. Claim 1

Claim 1 is directed to a tool for making an incision in and removing tissue from a vessel wall, where that tool comprises a cutter (4) and a piercing member (6) positioned within the cutter (4), wherein the piercing member (6) and the cutter (4) are configured to translate together to penetrate the wall of the vessel.¹ Claims 2-15 depend from independent claim 1, and thus add additional limitations to those present in independent claim 1.

¹ E.g., Specification, page 3, lines 13-24; page 6, line 24 through page 10, line 19; page 26, line 3 through page 30, line 13; Figures 1-5, 13 (exemplary reference characters indicated in text above).

B. Claim 17

Claim 17 is directed to a surgical tool for removing tissue from the wall of a vessel to create an opening, where that tool comprises a rotatable cutter (4); an auger assembly (10) fixed to and substantially coaxial with the cutter (4), the auger assembly (10) comprising an auger (6) at its distal end; and an actuator (24) connected to at least one of the auger assembly (10) and the cutter (4).² Claims 18-51 depend from independent claim 17, and thus add additional limitations to those present in independent claim 17.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-15

Independent claim 1 stands finally rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,825,362 to Hougen (“Hougen”). Dependent claims 5-6 and 8-14 also stand rejected under Hougen. Independent claim 1 also stands finally rejected under 35 U.S.C. §102(b) as being anticipated by the St. Jude Medical Instructions for Use.”³ Dependent claims 7 and 15 also stand finally rejected under that reference.

B. Claims 17-51

Independent claim 17 and dependent claims 18-31, 33-39 and 51 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Hougen.

² E.g., Specification, page 3, lines 13-24; page 4, lines 13-17; page 6, line 24 through page 11, line 18; page 26, line 3 through page 30, line 13; page 31, line 20 through page 32, line 10; Figures 1-5, 13 (exemplary reference characters indicated in text above).

³ Office Action of May 18, 2006 (“Final Action”); page 3, and Notice of Non-Compliance of October 31, 2006. As the Notice of Non-Compliance acknowledges on page 2, the St. Jude Medical Instructions for Use are part of

VII. ARGUMENTS

A. The Cited Art Does Not Anticipate the Claims

The MPEP sets forth the legal standard of anticipation under 35 U.S.C. §102: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”⁴ (emphasis added).

1. Claims 1-15

Claim 1 claims a “tool for making an incision in and removing tissue from a vessel wall, comprising: a cutter; and a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel.”

As claimed, both the piercing member and the cutter “translate together to penetrate the wall of the vessel.” As set forth in the specification, the phrase “translate together” means that the piercing member and the cutter are “fixed axially, but independent rotationally.”⁵ “That is, the auger and the cutter are fixed [to one another] with respect to translation, but not with respect to rotation.”⁶ Thus, the piercing member and the cutter are fixed to one another with respect to translation “to penetrate the wall of the vessel.”

In contrast, Hougen neither expressly nor inherently describes the claimed piercing member and cutter configured to translate together to penetrate the wall of a vessel. Hougen discloses a pointed pilot pin 42 coaxial with an annular hole cutter 14.⁷ The Office Action

the reference submitted on May 27, 2005 entitled “Cardica PAS-Port Proximal Anastomosis System 510(k), Section VI.C, “Substantial Equivalence,” and Attachment 7.”

⁴ MPEP 2131 (quoting *Verdegaal Brothers v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

⁵ Specification; page 8, lines 17-19.

⁶ *Id.*; page 3, lines 21-22.

⁷ Hougen; e.g., col. 2, lines 36-37, 59-62; Figures 2-4, 6-15.

analogizes the pilot pin 42 of Hougen to the claimed piercing member, and analogizes the cutter 14 of Hougen to the claimed cutter.⁸ As the tool of Hougen is actuated, the “pilot pin 42 progressively retracts as cutter 14 advances into the workpiece.”⁹ That is, the pilot pin 42 and the cutter 14 translate in opposite directions to cut a hole in the workpiece. The pilot pin 42 and the cutter 14 are therefore not fixed to one another in translation, because they translate in different directions relative to one another to cut a hole in the workpiece. Such relative motion of the pilot pin 42 and cutter 14 is consistent with one of the express objects of the invention, which is to “permit the pilot drill to retract easily after the cutter has initiated its hole cutting groove so as to minimize the axial force required to feed the cutter through the workpiece.”¹⁰ Based on this clear written description of Hougen, the statement in the Final Action that the “cutter and piercing member of Hougen...are fixed together as one-unit device [sic]” is simply wrong.¹¹ Because Hougen discloses only a pilot pin 42 and cutter 14 that move in opposite directions to cut a hole in a workpiece, Hougen does not and cannot disclose a piercing member and a cutter that translate together to penetrate the wall of a vessel, and Hougen neither expressly nor inherently describes each and every element claimed in claim 1.

Further, claim 1 is directed to a surgical tool, and requires that “said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel” that is identified in the preamble. However, the device of Hougen is a “machine tool” that is used to make holes in “conduit, a vehicle frame or body member, etc.” (Hougen; col. 1, lines 63-65; col. 2, lines 50-51). As a result, Hougen discloses nothing about a piercing member and cutter that are configured to translate together to penetrate the wall of a vessel.

⁸ Final Action, page 2.

⁹ Hougen; col. 4, lines 1-2; e.g., Figures 2-3, 12-14. (emphasis added).

¹⁰ *Id.*, col. 1, lines 47-57.

¹¹ Final Action; page 3.

Turning to the St. Jude Medical Instructions for Use, that document also neither expressly nor inherently describes the claimed piercing member and cutter configured to translate together to penetrate the wall of a vessel. The St. Jude Medical Instructions for Use discloses a needle positioned within a cutter blade, where that needle is movable in translation relative to the cutter blade.¹² As an initial step in usage of that tool, users “fully advance the needle by pushing [a] button forward until it stops,” after which the needle is inserted through the aortic wall.¹³ At this point, the distal end of the needle is extended a significant distance distal to the cutter blade.¹⁴ Next, the button is released “to allow the needle to engage the inside wall of the aorta,” such that the needle retracts proximally relative to the cutter blade and is closer to the cutter blade than in the previous step.¹⁵ Next, the user is directed to “[r]otate the cutter blade to advance through the aorta until the hole is complete.”¹⁶ This advancement takes place while the needle is substantially stationary, such that after the cutter blade has advanced, the distal end of the needle is even closer to the cutter blade than in the previous step.¹⁷ Thus, the needle and cutter blade translate relative to one another throughout the entire cutting process, and therefore are not fixed to one another with respect to translation “to penetrate the wall of the vessel.” Consequently, the needle and cutter blade of the St. Jude Medical Instructions for Use do not “translate together to penetrate the wall of the vessel” as required by claim 1, and the St. Jude Medical Instructions for Use do not expressly or inherently describe each and every element of claim 1.

¹² St. Jude Medical Instructions for Use; page 7; Figures 13-15.

¹³ *Id.*; page 7, Figure 13.

¹⁴ *Id.*

¹⁵ *Id.*; page 7; Figure 14.

¹⁶ *Id.*, page 7; Figure 15. (emphasis added).

¹⁷ *Id.*

None of the references expressly or inherently describes each and every element claimed in claim 1, and as a result claim 1 is believed to be in condition for allowance. Claim 1 was acknowledged as generic in the Office Action of August 24, 2005, so allowance of generic claim 1 would be as to all species. Claims 2-15 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 9, the claim requires that “said piercing member holds the tissue removed from the wall of the vessel.”¹⁸ However, the “primary object” of the Hougen is “ejecting the round slug formed by the cutter from within the cup portion of the cutter upon completion of the hole cutting operation.”¹⁹ “Ejecting” is the opposite of the claimed “holding.”

With regard to claim 10, the claim term “hemostatic” is related to the flow of blood. Blood, much less blood flow, is not expressly or inherently described in Hougen. Thus, Hougen does not and cannot disclose a cutter that is substantially hemostatic.

2. Claims 17-31, 33-39 and 51

Claim 17 claims a “surgical tool for removing tissue from the wall of a vessel to create an opening, comprising: a rotatable cutter; an auger assembly fixed to and substantially coaxial with said cutter, said auger assembly comprising an auger at its distal end; [and] an actuator connected to at least one of said auger assembly and said cutter.”

Because the claimed auger assembly is “fixed to” the cutter, it is necessarily translationally fixed to the cutter. “Because the auger and the cutter are fixed to one another, they rotate and advance together to penetrate the wall of a tubular vessel and cut tissue from

¹⁸ Emphasis added.

¹⁹ Hougen; col. 1, lines 32-36.

it.”²⁰ The auger assembly includes an auger at its distal end, such that the auger is also translationally and rotationally fixed to the cutter.

The argument set forth above with regard to claim 1 applies equally here. The pilot pin 42 and the cutter 14 of Hougen move in opposite translational directions to cut a hole in the workpiece. The pilot pin 42 and the cutter 14 are therefore not fixed to one another in translation, because they translate in opposite directions relative to one another to cut a hole in the workpiece. Consequently, Hougen does not expressly or inherently disclose “an auger assembly fixed to...said cutter, said auger assembly comprising an auger at its distal end.”

None of the references expressly or inherently describes each and every element claimed in claim 17, and as a result claim 17 is believed to be in condition for allowance. Claims 18-53 depend from claim 17, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Dependent claim 21 claims “an actuator [that] extends away from the axis of said cutter.” The Final Action analogizes the spring 70 of Hougen to the claimed actuator.²¹ However, the spring 70 of Hougen extends along the axis of the cutter, and at no point extends away from the axis of the cutter, as required by claim 21.²²

Dependent claims 23-24 claim “at least one centering flange between and connected to said auger and said cutter.” The Final Action fails to point to any structure in Hougen analogous to the claimed centering flange, acknowledging that no such structure exists in Hougen.

Dependent claim 25 claims, among other elements, “a casing, said casing comprising a contact structure at its distal end.” The claimed casing is substantially hollow, and protects

²⁰ Specification; page 3, lines 14-16.

²¹ Final Action; page 2.

²² Hougen; e.g., Figures 2-4, 6-9.

one or more of the claimed components.²³ “The contact structure 110 is placed against the vessel to substantially stabilize its surface within the perimeter of the contact structure 110, such that the tubular vessel is not substantially flattened by the pressure applied to it via the contact structure 110.”²⁴ The casing is separate from the auger and the cutter, and its distal end is configured for placement on the workpiece vessel. In contrast, Hougen discloses no structures other than the pilot pin 42 and the cutter 14 configured for placement on the workpiece. The Final Action analogizes the guide bushing 24 of Hougen to the claimed casing.²⁵ However, the guide bushing 24 does not contact, and is not configured for contact with, the workpiece; indeed, the washer 46 would prevent the guide bushing 24 from contacting the workpiece even if the guide bushing 24 were able to move forward toward the workpiece.²⁶

Dependent claim 30 claims “a seal housing; and an introducer tip connected to said seal housing, wherein said auger and said cutter are configured to slide through said introducer tip.” Referring to the specification, “[t]he seal housing 34 is a substantially hollow structure into which the proximal end of the auger assembly 10 extends.”²⁷ “The seal housing 34 includes an opening 36 at or near its distal end through which the introducer tip 28 and the auger assembly 10 extend.”²⁸ “The introducer tip 28...is a radially and bilaterally symmetrical shell.”²⁹ “The introducer tip 28 follows the cutter 4 and the auger 6 into the vessel wall, and remains in the opening thus formed, in order to provide hemostasis with

²³ Specification, page 19, lines 2-4; Figure 11.

²⁴ *Id.*; page 25, lines 18-21.

²⁵ Final Action; page 2.

²⁶ Hougen; e.g., Figures 2-4.

²⁷ Specification, page 12, lines 17-19; Figures 1, 4, 11.

²⁸ *Id.*, page 12, lines 19-20.

²⁹ *Id.*, page 11, lines 20-23

regard to that opening....Fluid such as blood enters the seal housing 34 through the introducer tip 28, and the seal housing 34 maintains hemostasis with regard to the fluid in the vessel.”³⁰ Thus, the introducer tip 28 and seal housing 34 are substantially hollow structures that maintain hemostasis of a vessel after the cutter 4 and auger 6 have made an opening in the wall of that vessel.

The Final Action characterizes the yoke 28 of Hougen as analogous to the claimed seal housing.³¹ The Final Action further characterizes the U-shaped opening 30 in the yoke 28 as analogous to the claimed introducer tip.³² The yoke 28 is a component of a hole-cutting fixture 10, where the U-shaped opening 30 extends around the arbor 16 of the tool.³³

Neither the yoke 28 nor the U-shaped opening 30 are substantially hollow structures that can maintain hemostasis of a vessel after an opening has been made in that vessel. The yoke 28 is just a flat piece of material with a U-shaped opening 30 defined therein. Further, a U-shaped opening 30 in anything is not and cannot be “a radially and bilaterally symmetrical shell” that is the claimed introducer tip. Thus, Hougen neither expressly nor inherently describes the claimed seal housing or introducer tip.

Dependent claim 33 claims, among other elements, a seal housing that comprises at least one guide. The seal housing 34 is described in the specification, as set forth above. Each guide “is defined in or connected to the inner surface of the seal housing 34.”³⁴ However, as established above, Hougen fails to disclose a seal housing, and consequently does not and cannot disclose a seal housing that comprises at least one guide.

³⁰ *Id.*, page 27, lines 15-21.

³¹ Final Action; page 2.

³² *Id.*; page 2.

³³ Hougen; col. 2, lines 34-46; Figure 1.

³⁴ Specification, page 14, line 1.

Dependent claim 34 claims “a bushing connected to said coil spring, said bushing comprising at least one guide follower configured to engage said guide.” As shown above, Hougen fails to disclose a guide, and thus cannot disclose a bushing configured to engage the claimed guide.

Dependent claim 38 claims “an impulse source configured to rotate and translate said auger and said cutter.” The Final Action fails to point to any structure in Hougen analogous to the claimed impulse source, acknowledging that no such structure exists in Hougen.

VII. CONCLUSION

For the above reasons, Applicants respectfully submit that the Final Action’s rejection of pending claims 1-15, 17-31, 33-39 and 51 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed.

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Respectfully submitted,



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APPENDIX 1 -CLAIMS

1. A tool for making an incision in and removing tissue from a vessel wall, comprising:
 - a cutter; and
 - a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel.
2. The tool of claim 1, wherein said piercing member is configured to allow rotation relative to said cutter.
3. The tool of claim 1, wherein said piercing member is rotationally fixed to said cutter.
4. The tool of claim 1, wherein said cutter is a curved blade having a substantially circular distal end.
5. The tool of claim 1, wherein said cutter is a curved blade having an open perimeter at its distal end.
6. The tool of claim 1, wherein the distal end of said cutter is beveled inward.
7. The tool of claim 1, wherein the distal end of said cutter is beveled outward.
8. The tool of claim 1, wherein the distal tip of said piercing member extends further in the

distal direction than the distal end of said cutter.

9. The tool of claim 1, wherein said piercing member holds the tissue removed from the wall of the vessel.

10. The tool of claim 1, wherein said cutter is substantially hemostatic.

11. The tool of claim 1, wherein said piercing member is an auger.

12. The tool of claim 11, wherein said auger and said cutter are substantially coaxial.

13. The tool of claim 11, wherein said auger comprises:

a spike;

a shaft connected to and extending distally from said spike, said shaft fixed to said cutter.

14. The tool of claim 13, wherein said spike is substantially conical at its distal end.

15. The tool of claim 14, wherein the width of the proximal end of said spike is greater than the width of said shaft.

17. A surgical tool for removing tissue from the wall of a vessel to create an opening, comprising:

a rotatable cutter;

an auger assembly fixed to and substantially coaxial with said cutter, said auger assembly comprising an auger at its distal end;
an actuator connected to at least one of said auger assembly and said cutter.

18. The surgical tool of claim 17, wherein said actuator is a flexible shaft.

19. The surgical tool of claim 17, wherein said actuator is a coil spring.

20. The surgical tool of claim 17, wherein said actuator is retractable.

21. The surgical tool of claim 17, wherein said actuator extends away from the axis of said cutter.

22. The surgical tool of claim 17, wherein said cutter is vented.

23. The surgical tool of claim 22, wherein said auger further comprises at least one centering flange between and connected to said auger and said cutter, wherein each said centering flange comprises a slot extending therethrough.

24. The surgical tool of claim 23, wherein at least one centering flange comprises a substantially circumferential groove defined therein.

25. The surgical tool of claim 17, further comprising a casing, said casing comprising a contact structure at its distal end, wherein said auger and said cutter translate relative to said

contact structure.

26. The surgical tool of claim 25, wherein said contact structure has an open perimeter.
27. The surgical tool of claim 25, wherein said auger and said cutter translate distally a selected amount relative to said contact structure.
28. The surgical tool of claim 17, further comprising a knob operatively connected to said coil spring.
29. The surgical tool of claim 28, wherein said knob is rotatable through two or more positions, and wherein actuation of said auger and said cutter is controlled by rotation of said knob.
30. The surgical tool of claim 17, further comprising a seal housing; and an introducer tip connected to said seal housing, wherein said auger and said cutter are configured to slide through said introducer tip.
31. The surgical tool of claim 30, wherein said auger and said cutter are configured for withdrawal into said seal housing.
32. The surgical tool of claim 30, wherein said introducer tip is expandable.

33. The surgical tool of claim 30, wherein said seal housing comprises at least one guide.
34. The surgical tool of claim 33, further comprising a bushing connected to said coil spring, said bushing comprising at least one guide follower configured to engage said guide.
35. The surgical tool of claim 33, wherein said introducer defines a first axis, and wherein said guide extends away from said first axis.
36. The surgical tool of claim 33, wherein said introducer defines a first axis, and wherein said coil spring is moveable in a direction at an angle to said first axis.
37. The surgical tool of claim 17, wherein the distal end of said auger extends distally beyond the distal end of said cutter.
38. The surgical tool of claim 17, further comprising an impulse source configured to rotate and translate said auger and said cutter.
39. The surgical tool of claim 38, wherein said impulse source is a spring.
40. The surgical tool of claim 38, further comprising:
- a rotatable first driveshaft connected to said coil spring; and
- a axially fixed first gear comprising an opening through which said first driveshaft extends, wherein said first driveshaft is slidable relative to said first gear, and wherein rotation of said first gear causes said first driveshaft to rotate.

41. The surgical tool of claim 40, wherein said first driveshaft comprises at least one rib aligned extending substantially radially outward and said first gear comprises a passage therethrough configured to engage said at least one rib.
42. The surgical tool of claim 41, wherein said at least one rib extends substantially axially along said first driveshaft.
43. The surgical tool of claim 40, further comprising a carriage having a threaded passage therein, said first driveshaft further comprising a threaded portion configured to engage said threaded passage, wherein rotary motion of said first driveshaft causes said first driveshaft to translate distally relative to said carriage.
44. The surgical tool of claim 43, further comprising:
 - a second driveshaft; and
 - a second gear connected to said second driveshaft, said second gear configured to engage said first gear, wherein rotation of said second gear causes said first gear to rotate.
45. The surgical tool of claim 44, further comprising at least one registration member extending from at least one of the second driveshaft and the second gear.
46. The surgical tool of claim 45, wherein at least one said registration member is configured to restrain said second driveshaft against rotational motion and allow translational motion.

47. The surgical tool of claim 44, further comprising:
- a cam cylinder operationally connected to said auger and said cutter, said cam cylinder comprising at least one cam path defined therein; and
- a knob connected to said cam cylinder.
48. The surgical tool of claim 47, wherein said auger and said cutter are actuated based on the position of said knob.
49. The surgical tool of claim 47, further comprising:
- an introducer tube;
- a first cam follower connected to said introducer tube; and
- a second cam follower connected to said carriage;
- wherein each said cam follower rides within one said cam path.
50. The surgical tool of claim 49, wherein rotation of said cam cylinder causes said at least one cam path to move relative to and cause translation of at least one said cam follower.
51. The surgical tool of claim 38, wherein said impulse source imparts angular and linear momentum to said auger and said cutter before said auger and said cutter contact the wall of the vessel.

APPENDIX 2 – EVIDENCE APPENDIX

None.

APPENDIX 3 – RELATED PROCEEDINGS APPENDIX

None.